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14 UNITED STATES DISTRICT COURT
15 NORTHERN DISTRICT OF CALIFORNIA
16 SAN FRANCISCO DIVISION
17

18 THE CITY AND COUNTY OF SAN
FRANCISCO, CALIFORNIA and THE
19 PEOPLE OF THE STATE OF CALIFORNIA,
Acting by and through San Francisco City
Attorney DAVID CHIU,

20 Plaintiff,
21

22 v.
23

24 PURDUE PHARMA L.P., et al.
25

26 Defendants.
27
28

Case No. 3:18-cv-07591-CRB

**THE PEOPLE'S PRELIMINARY
OUTLINE OF PROPOSED
FINDINGS OF FACT AND
CONCLUSIONS OF LAW**

Judge: Honorable Charles R. Breyer

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1 I. INTRODUCTION

2 The People of the State of California, acting by and through the San Francisco City
 3 Attorney David Chiu, seek recovery to abate a public nuisance, the ongoing opioid
 4 epidemic in San Francisco. This opioid epidemic has affected, and interfered with, the
 5 public health and other public rights in San Francisco. Each of the Defendants caused or
 6 contributed to the creation and/or maintenance of this public nuisance. In addition, the
 7 same behavior that contributed to the nuisance also violated California's Unfair
 8 Competition Law through conduct over a period of many years that was deceptive,
 9 unlawful, and unfair.

10 The nuisance in San Francisco was caused by an oversupply of opioids and, in
 11 particular, by a flood of opioids into San Francisco that should not have been there. The
 12 greatest risk factor for "opioid use disorder" (OUD) – the medical term that encompasses
 13 both the popular conception of "addiction" as well as other misuse of opioids – is
 14 exposure to opioids. When opioids are widely available, a certain percentage of people
 15 exposed to them will develop OUD; those who never encounter opioids do not develop a
 16 problem with them. Moreover, with an increased supply of opioids, and increased
 17 incidence of OUD, come a host of other problems, including overdoses and overdose
 18 deaths; illegal markets for opioids developed to feed the habits of those who have become
 19 addicted; and increased use of illegally-manufactured drugs, including heroin and street
 20 fentanyl, and the attendant harms that flow from such use.

21 The opioids that should not have been in San Francisco, the oversupply, got here in
 22 two distinct ways, each of which was the result of the Defendants' misconduct. First,
 23 prescription opioid manufacturers and others working with them engaged in campaign of
 24 false and misleading statements about prescription opioids, for the purpose of undoing
 25 decades of medical understanding of the risks and benefits of opioids and changing the
 26 paradigm for opioid use. These false and misleading statements included representations
 27 that the drugs were safe, that patients rarely become addicted, that dosages need not be
 28 limited or monitored, and that opioids approved specifically for cancer pain could and

1 should be safely prescribed for non-cancer patients. Doctors, who were misled by this
2 campaign of false and misleading statements, wrote opioids prescriptions in
3 unprecedented numbers, bringing vastly increased amounts of opioids into San Francisco
4 and exposing thousands of patients to opioids who would not otherwise have encountered
5 them. This vast increase in opioid prescribing was driven by medically inappropriate
6 prescriptions, that is, prescriptions that would not be medically justified by a proper
7 understanding of the risks and benefits of the drugs. Predictably, as the number of opioid
8 prescriptions went up, so did the number of people with OUD. All of the Defendants in
9 this case participated in the campaign to promote opioids through these
10 misrepresentations.

11 The second pathway of opioid oversupply was diversion. With increased
12 availability and prescriptions for opioids came increased diversion into illegal markets and
13 for inappropriate use, aided by unscrupulous doctors who exploited the new environment
14 of permissive use, as well as unscrupulous “patients” who manipulated doctors to
15 prescribe drugs that could be sold in illegal markets. The risk of diversion of prescription
16 opioids has long been understood – because of the addictive nature of these drugs, there is
17 an active illegal market. To address the problem of diversion, the manufacture, sale and
18 dispensing of opioids are tightly controlled under the federal Controlled Substances Act
19 (“CSA”). As described below, the statute and regulatory framework mandate a “closed
20 system” in which, in order to manufacture, distribute or dispense opioids, a person or
21 entity must register with the Drug Enforcement Administration. All registrants under the
22 CSA are required to provide “effective controls against diversion.” As discussed in detail
23 below, all of the Defendants were obliged to maintain such controls, but none of them did
24 so in a meaningful way. All of the Defendants had information in their possession that
25 allowed them to identify situations where there was a meaningful risk of diversion, and all
26 of them routinely disregarded this information in order to keep selling more opioids.

27 Together, the oversupply of opioids that resulted from Defendants’ false and
28 misleading statements and from Defendants’ failure to control against diversion flooded

1 San Francisco with prescription opioids, predictably and foreseeably contributing to the
 2 public health crisis – the nuisance – for which the People now seek to hold the Defendants
 3 accountable.

4 This document will provide an outline of the facts to be shown at trial, and of the
 5 conclusions of the law the People expect to ask the Court to draw at the end of the case; it
 6 will be updated and fleshed out as the evidence supporting the People’s case is admitted at
 7 trial. Because of the preliminary nature of this submission, and the fact that no evidence
 8 has yet been submitted, this document is necessarily provisional and is not intended to be
 9 comprehensive nor to describe all of the evidence that the People may submit at trial.
 10 And to the extent the composition of the Defendants changes over the course of the trial,
 11 the approach the People elect to take may change and with it the substance of this
 12 document.

13 **II. PRELIMINARY OUTLINE OF PROPOSED FINDINGS OF FACT**

14 **A. Defendants**

15 Defendants in this action are: (1) three “families” of opioid manufacturers, known
 16 generally as the Endo, Allergan, and Teva Defendants; (2) Anda, a wholesale distributor
 17 of opioids; and (3) Walgreen Co., which acted as a wholesale distributor to its own stores
 18 and continues to act as a dispenser of opioids through the large chain of pharmacy stores it
 19 owns and operates across the United States, and in San Francisco, where it maintains a
 20 dominant market share. The Endo, Allergan, and Teva Defendant families consist of
 21 multiple corporations that have been named as Defendants here. These entities are listed
 22 in Appendix A.

23 To complicate matters, certain of the Allergan and Teva entities have been
 24 historically intertwined, especially with respect to certain entities referred to as the
 25 “Watson/Actavis” entities. These entities operated first under the name Watson, then
 26 under the name Actavis, then became part of the Allergan defendant family, and were
 27 later sold by Allergan to Teva. The entities that were sold to Teva manufacture and sell
 28 generic opioids; other portions of the Watson/Actavis business that manufacture and sell

1 certain branded opioids remain part of the Allergan family. The People understand that
 2 Teva and Allergan entered into an indemnity agreement when Allergan sold its generic
 3 opioid business to Teva, but that they do not agree as to the meaning and effect of that
 4 agreement on their respective liabilities in this case. The People do not believe that the
 5 indemnity agreement between Allergan and Teva has any effect on whether or to what
 6 extent those entities or their affiliates are liable to the People in this case.

7 Anda is also intertwined with Allergan and Teva. It is a wholesale distributor that
 8 sold branded and generic opioids manufactured by several pharmaceutical companies.
 9 Anda was at one point part of Watson and then Allergan; it was acquired by Teva from
 10 Allergan in 2016 along with the other entities discussed above.

11 Walgreen Co. is a national chain that operates retail pharmacy stores all over the
 12 United States under the name “Walgreens,” where it dispenses prescription opioids.
 13 Walgreens maintains a particularly strong presence in San Francisco, where it operates
 14 approximately 50 retail stores in San Francisco (down from a high watermark of around
 15 70 stores). Until approximately 2014, Walgreens also distributed prescription opioids to
 16 its own stores.

17 **B. Background**

18 1. *Opioids and Their Addictive Properties*

19 Addiction is a chronic, relapsing and remitting disease with a behavioral
 20 component, characterized by neuroadaptive brain changes resulting from exposure to
 21 addictive drugs. Every human being has the potential to become addicted. Some are
 22 more vulnerable than others. Risks for becoming addicted include genetic,
 23 developmental, and environmental factors (nature, nurture, and neighborhood). The
 24 biggest risk factors for addiction is simple access to addictive drugs. When supply of an
 25 addictive drug is increased, more people misuse and suffer the harms of that drug.

26 From a neuroscience perspective, addiction is a disorder of the brain’s reward
 27 circuitry. Opioids, which relieve pain by binding to the mu-pain receptors, also cause the
 28 release of the neurotransmitter dopamine. In order to accommodate the high amount of

1 dopamine released, the brain adapts by downregulating its own internal dopamine and its
2 own internal dopamine receptors. This process is called neuroadaptation, and the result is
3 a dopamine deficit state, wherein the threshold for experiencing pleasure goes up, and the
4 threshold for experiencing pain goes down. Individuals struggling with addiction then
5 need the substance not to feel good, but to escape the pain of withdrawal. In advanced
6 stages of addiction, individuals commit all available resources to obtaining more of the
7 substance, even forgoing natural rewards like food, finding a mate, or raising children. By
8 hijacking the brain's reward and motivational centers, addiction leads to compulsive, self-
9 destructive consumption that overcomes the limits of voluntary choice.

10 Among addictive substances, opioids are uniquely dangerous, for at least three
11 reasons. First, they are sold as medicine, normalizing their use and propagating a
12 misleading safety profile, with devastating consequences. Second, through increasing
13 tolerance, they create a debilitating dependence such that painful withdrawal leads to a
14 vicious cycle of drug-seeking and withdrawal. Third, they kill quickly; the course of
15 addiction is extremely rapid compared to other addictive substances, potentially
16 destroying lives within months, and even a single exposure in an opioid naïve person can
17 lead to death.

18 2. *History of Opioid Use and Prescribing*

19 Opioids have been known as addictive, potentially poisonous drugs since antiquity
20 and their special dangers widely recognized. In the 19th century, after the isolation of
21 morphine and the invention of the hypodermic syringe, it was wrongly assumed that
22 opioids administered by a doctor using a syringe would not be addictive. During the Civil
23 War, opium, laudanum, and hypodermic morphine were used extensively to treat soldiers
24 and Victorian housewives alike. Hypodermic morphine soon became the major driver of
25 American's first opioid epidemic. Hundreds of reports in late nineteenth century medical
26 journals detailed iatrogenic (physician-initiated) cases of morphine addiction. The risk of
27 addiction increased in cases where doctors continued to administer hypodermic morphine
28 over long periods of time for protracted illnesses. The two most important risk factors

1 were exposure to opioids and a history of chronic illness.

2 In the 1870s and 1880s, America's per capita consumption of opioids tripled. In
3 1897, Bayer chemists, trying to find a less addictive form of morphine, synthesized
4 heroin. Heroin was marketed by Bayer as a cough and cold remedy alongside Bayer
5 Aspirin from 1898 to 1910.

6 The opioid addiction epidemic of the late 19th and early 20th century led to ever-
7 stricter laws and regulations regarding the prescribing and dispensing of opioids in
8 medical practice, beginning, at the federal level, in the early 1900s with the Harrison
9 Narcotic Act, which effectively made heroin illegal. (As in many other areas, California
10 was a trend-setter: it was home to the first local ordinances restricting opioid sales,
11 starting with San Francisco's 1875 ban on non-pharmacy sales, adopted statewide in
12 1881.) By the end of the 19th century, leading physicians had reached consensus that
13 opioids were dangerous and should be used as sparingly as possible, almost exclusively
14 for short-term, acute pain or end-of-life palliative care (primarily in the context of cancer).
15 The evidence-based conservative standard of care was consistent, widespread, and quite
16 durable. Medical training and education throughout the 20th century, save for the last two
17 decades, was filled with warnings about the addictive potential of medicinal opioids, even
18 when prescribed to patients with severe pain and dire illness, but especially when used
19 long-term in the treatment of chronic pain. Perhaps as a result, subsequent opioid
20 epidemics in the 1940s and 1970s were smaller-scale heroin epidemics unrelated to
21 medical prescribing. They were targeted and quelled through a process of repatriating
22 Vietnam War veterans, criminalization, and methadone maintenance treatment.

23 In 1970, Congress enacted the CSA, which serves as the cornerstone of today's
24 drug scheduling system. The impetus for the new law came in part from a disastrous
25 experiment in the late 1950's and early 1960's with looser restrictions on one particular
26 opioid – an Endo product marketed under the name Percodan that combined oxycodone
27 and aspirin. Endo (not the same entity named as defendant here) claimed that Percodan
28 was less addictive than other opioids, and for a time it was successful in having Percodan

1 subject to less restrictive regulation, especially in California. Sales and addiction spiked,
2 and the regulations applicable to other opioids were put back in place for Percodan. The
3 Percodan fiasco was one of the triggers for the push that emerged in the late 1960's for
4 stronger regulation of prescription drugs, leading, ultimately, to the enactment of the CSA,
5 the provisions of which are described below.

6 In 1990, as part of the broader pain reform movement, California passed an
7 Intractable Pain Treatment Act ("IPTA") that expanded care options for pain patients by
8 protecting physicians from Board discipline when they "prescribe or administer controlled
9 substances" to treat a "diagnosed condition causing intractable pain." *See* Cal. Bus. &
10 Prof. Code § 2241.5. It expanded medical opioid availability, but did so cautiously in
11 several ways. First, it defined intractable pain as pain that could not be relieved or cured
12 "after reasonable efforts," meaning that opioids were still seen as a last resort: a physician
13 had to try other "reasonable" approaches to treating the pain first. Second, it excluded
14 opioids provided to a person known to be using drugs or substances for "nontherapeutic
15 purposes." In other words, the law discouraged prescribing opioids to a group with
16 known addiction risks. Finally, the law clearly affirmed the Board's authority to require
17 the usual consumer protection standards: limiting to legitimate therapeutic purposes,
18 requiring record-keeping and continuing to require that the use of opioids be consistent
19 with "public health and welfare." Although the statute was a significant change to the
20 state's opioid policies, recognizing limited circumstances where long-term opioids to be
21 prescribed for reasons other than palliative (end-of-life) care, it did not upend California's
22 long-standing guardrails to protect the public from opioids, or the federal statutes
23 requiring those companies in the opioid supply chain to exercise important controls.
24 Instead, it retained most of those safeguards, particularly for known at-risk groups. More
25 importantly, it did not reflect a change in understanding of the risks of opioid therapy – it
26 simply recognized that, when opioids are carefully prescribed and managed, there might
27 be limited, additional circumstances in which those risks could be outweighed by potential
28 benefits to those for whom other pain treatments had failed.

1 In 1997, after intensive lobbying by the pharmaceutical industry, California
2 enacted the Pain Patients' Bill of Rights ("PPBR"), *see* Cal. Health & Safety Code
3 §§ 124960-961. The PPBR recognized that opioids might be appropriate treatment for the
4 control of pain in a variety of circumstances and sought to ensure that patients would have
5 access to them when appropriate. The PPBR did not, however, adopt particular guidelines
6 for when opioids are appropriate, nor did it set forth the risks and benefits of the drugs.
7 Rather, it deferred to the judgment of physicians to determine when and for whom opioids
8 are appropriate. *See* §§ 124960(f) (stating that opioids therapy may be safe "in the hands
9 of knowledgeable, ethical, and experienced pain management practitioners"); 124961(c)
10 (allowing physicians to refuse to prescribe opioids); 124961(d) (deferring to physicians to
11 choose appropriate dosage). In many instances, it also required doctors to act in
12 accordance with the IPTA, which, as noted above, left in place many of the traditional
13 prescribing guardrails. *See* §§ 124960((d), (j), 124961(b), (d). It granted doctors greater
14 autonomy in deciding how and when to prescribe opioids.

15 The PPBR's emphasis on, and deference to, the judgment of prescribing physicians
16 made it all the more important that doctors be properly informed about the risks and
17 benefits of opioid therapy, so that they could make appropriate prescribing decisions for
18 their patients. Doctors who were misinformed about the safety and efficacy of opioid
19 therapy were unable properly to exercise the broad discretion granted to them by the
20 PPBR. Moreover, the PPBR made it easy for drug companies to influence prescribers and
21 increase prescribing through false and misleading representations; instead of having to
22 convince the medical establishment to change specific guidelines, Defendants needed only
23 to mislead newly-empowered doctors, one physician at a time. As described below, the
24 proved adept at this.

25 The opioid crisis that emerged beginning in the middle 1990's, which runs through
26 today, reflected an abandonment (orchestrated by Defendants and others in the industry)
27 of the prior conservative consensus about the need to restrict opioid prescribing. How
28 that change came about – and the role of the Defendants in altering that consensus – is

discussed below. In short, however, the supply of prescription opioids dramatically increased, nationwide and in San Francisco, when doctors, through a massive and coordinated campaign of misrepresentations about the risks and benefits of opioids, were persuaded to forget the hard lessons learned in the 19th century and to prescribe opioids freely under the mistaken impression (already disproved by the close of the 19th century) that patients taking opioids for pain do not become addicted. As a result, the supply of prescription opioids was increased – and dangerously so – by both increases in medically inappropriate prescribing by doctors misled by Defendants’ false and misleading messaging. As the number of prescriptions went up, so, too, did diversion, facilitated by unscrupulous doctors and patients, further increasing the supply of prescription opioids. While only a percentage of those who have been prescribed opioids will go on to problematic use (albeit a significant and all-too-high percentage), each and every diverted opioid by definition is being misused. Thus, the actual harms of diverted opioids are disproportionate to the number of diverted pills, when compared to the harms of inappropriately, but validly, prescribed opioids.

Eventually, many doctors began to notice that what they had been told was untrue. Many patients prescribed opioids for pain *did* become addicted, and greater caution in prescribing and greater care in management of opioid patients was clearly required. As a result, there was a decline in prescribing. But patients who were already addicted to opioids didn’t magically lose their dependence. As prescription opioids became harder to get or more expensive, many of these individuals turned to heroin and other illegally-manufactured opioids to feed the habits they had already developed.

C. The Crisis in San Francisco

The opioid epidemic has hit San Francisco especially hard. The huge increase in the availability of prescription opioids led here, as elsewhere, to dramatic increases in OUD, overdoses, and related problems. But the opioid epidemic in San Francisco occurred on the heels of a prior heroin problem that the City had been successfully managing, when it was overwhelmed by the influx of prescription opioids. This meant

1 that the timing and pattern of the opioid epidemic looks somewhat different in San
2 Francisco from elsewhere in the United States.

3 In the 1990s, heroin was a significant issue in San Francisco, with heroin overdose
4 deaths not uncommon through 1999. The City took swift and pioneering action to address
5 this problem. For example, in 2003, the San Francisco Department of Public Health
6 (SFDPH) partnered with a community-based program, the Drug Overdose Prevention and
7 Education Project (DOPE Project) to establish the first health-department sanctioned take-
8 home naloxone prescription program in the United States. SFDPH also opened methadone
9 and buprenorphine programs for people with opioid use disorder, and SFDPH doctors
10 began co-prescribing naloxone to patients receiving opioid prescriptions for pain. These
11 programs were remarkably successful. Beginning in 2000, these efforts began to slow the
12 high rate of heroin overdose deaths and by 2010 the number of people who died from
13 heroin-related overdose was down to approximately ten per year.

14 Unfortunately, during the same period, in the 1990s and 2000s, the supply of
15 prescription opioids dramatically increased, nationwide and in San Francisco for the
16 reasons described above and in more detail below. As a result of the increasingly large
17 supply of prescription opioids, the number of people using prescription opioids in San
18 Francisco increased significantly—as did the number of people dying from overdoses
19 related to prescription opioids. By 2010, San Francisco’s overdose death rate went up (to
20 between 100 and 150 people per year), with approximately 90% of deaths caused by
21 prescription pills.

22 During the 2010s, as the oversupply of prescription opioids began to wane, the
23 number of overdose deaths caused by prescription opioids decreased as well. But, as
24 noted, individuals who had developed OUD years earlier were psychologically and
25 chemically dependent on opioids. Accordingly, as prescription opioids became less
26 available, many turned to illegal sources. As a result, heroin use—and heroin overdose
27 deaths—increased again. Notably, however, prescription opioid involved deaths
28 continued to exceed those related to heroin and fentanyl combined well into the 2010s.

1 Although they reached a low around 2016, they then rose again through 2019. But overall,
2 while many parts of the country saw their total overdose numbers increase significantly
3 between 2010 and 2015, San Francisco did not. The City significantly increased its harm
4 reduction and treatment programs during these years: the DOPE Project alone was
5 responsible for 604 opioid overdose reversals in 2015—up more than one-thousand
6 percent (1000%) from 2010. Unfortunately, just when the City should have seen the fruits
7 of its investment in addressing opioid use in San Francisco, and when it should have been
8 able to turn its attention to other problems, it was forced in the latter half of the 2010s,
9 instead, to redouble its efforts to address the scourge of opioid addiction and to devote
10 significant additional resources to the problem.

11 The City's efforts were no match for illicitly-manufactured fentanyl. Some
12 prescription opioids include fentanyl, but the fentanyl that has appeared on the streets is
13 distinct from pharmaceutical fentanyl. It is wildly dangerous and turns up in unexpected
14 quantities and unexpected places; it is frequently used to “cut” heroin, so that users,
15 believing they are encountering only familiar heroin, can find themselves unexpectedly
16 exposed – often dangerously, and even fatally – to street-grade fentanyl. Street fentanyl
17 first spread on the East Coast and slowly began to show up in San Francisco in 2015-2016,
18 increasing substantially in 2018. With fentanyl on the scene, the number of opioid
19 overdose deaths increased over 478% from 101 in 2015 to 584 in 2020—more than double
20 the number of people who died of COVID-19 in 2020.

21 But opioid related deaths are only part of the tragic picture. The Zuckerberg San
22 Francisco General Hospital (ZSFG) Emergency Department (ED) handles approximately
23 15 to 20 opioid-related overdose incidents every day. The number of patients presenting
24 at the ZSFG ED with other opioid-related health conditions—including, for example,
25 sepsis, infections, or abscesses from unsterile injection practices—has also increased
26 steadily over the last six years. The impact of the opioid epidemic is so significant that in
27 a typical day about 25% of all visits to the ZSFG ED are opioid-related.

28 The opioid nuisance continues in San Francisco to this day. Nearly every resident

1 of San Francisco has been impacted in one way or another. Many thousands of people
 2 have a friend or family member struggling with addiction. Park rangers, street cleaners,
 3 even librarians have had to clean up needles, handle overdoses, and administer naloxone
 4 with alarming frequency. Libraries had to install special toilets to prevent blockages from
 5 the high volume of needles that people attempt to dispose of on a regular basis. Entire
 6 neighborhoods—like the Tenderloin—have been devastated. And residents’ enjoyment of
 7 public areas like sidewalks, parks, and libraries has been impeded citywide.

8 **D. Oversupply through Fraudulent and Misleading Statements and Unfair**
 9 **and Improper Promotion**

10 False, misleading, and overly aggressive promotion of prescription opioids led to a
 11 dramatic increase in the number of opioid prescriptions in San Francisco, far beyond what
 12 would have been appropriate to treat legitimate medical needs – referred to as the “false
 13 statement theory” in the Court’s summary judgment orders. (In fact, the Defendants’
 14 conduct encompassed both statements that were literally false and also many that were
 15 misleading, standing alone or in context.) Defendants, in general, overstated the benefits
 16 of opioid use, understated the risk of opioid addiction, minimized the risks associated with
 17 long term use, and engaged in improperly aggressive promotion for drugs that were
 18 unquestionably dangerous when misused. They did so as part of a concerted effort to alter
 19 the long-standing conservative consensus about opioid prescribing and to convince
 20 doctors that the hard lessons of the past did not apply to the newer generation of opioids
 21 Defendants were selling. In fact, there was little or no evidence to support their claims,
 22 which turned out to be, tragically, false. Moreover, Defendants knew their claims were
 23 false or knew, at a minimum, that they lacked any scientific basis for what they were
 24 saying.

25 *1. The False Messages and the Channels through Which They Were*
 26 *Conveyed*

27 There were several categories of misrepresentations disseminated by Defendants,
 28 the most prominent of which were: (1) the risk of addiction from chronic opioid therapy
 is low; (2) if opioid addiction occurs, it can be easily identified and managed; (3) signs of

1 addictive behavior are “pseudoaddiction,” which merely require more opioids; (4) opioid
2 withdrawal can be avoided with tapering; (5) opioid doses can be increased without limit
3 or greater risks; (6) long-term opioid use improves patient functioning; (7) alternative
4 forms of pain relief pose greater risks than opioids; and (8) new formulations of certain
5 opioids successfully deter abuse. None of these categories of misrepresentations directly
6 contradict the FDA’s decision that opioids were safe and effective for certain conditions,
7 but rather go beyond the FDA-approved labeling. Indeed, and tragically, the Defendants
8 misrepresented not only the dangers of opioid therapy, but also its benefits. They led the
9 medical community to believe that opioid therapy could bring pain relief indefinitely
10 when, in fact, the biochemistry of how opioids work means that, for many patients, relief
11 is temporary; in time, increasing doses of opioids are necessary to relieve the pain of the
12 opioids themselves, without being able offer true relief or improved functionality to the
13 patients now hooked on them.

14 Defendants knew that their opioid story would be more effective if it did not come
15 only from them and their sales force. To change the prescribing paradigm and expand
16 usage, Defendants engaged in a systematic and multi-pronged effort to communicate their
17 opioid messaging through a variety of channels.

18 **Sales Representatives:** Some of the false statements and misrepresentations did
19 come from company-employed sales representatives who were specifically trained to
20 present the messages described above. Those sales representatives “detailed” physicians
21 and other prescribers, encouraging them to prescribe certain branded opioids specifically,
22 reassuring them about the safety of opioids generally. The companies knew exactly which
23 health care providers were prescribing what opioid drugs because they purchased data on
24 prescribing activity to (1) strategically choose which prescribers to target for which opioid
25 sales presentations; (2) gauge whether their promotion efforts were working; and
26 (3) evaluate the performance of their sales representatives, including using weekly and
27 monthly prescription data to calculate “incentive compensation” and “sales contest”
28 winners.

1 **Paid Advocates:** Defendants also paid physician “key opinion leaders” to
2 communicate the various categories of false statements to their fellow physicians at
3 dinners, lunches, one-on-one meetings, and seminars. Certain Defendants maintained
4 “Speakers Bureaus,” with a roster of physicians on their payroll to deliver their message
5 to other doctors. In many instances, these “KOLs” would include discussions about “off
6 label” uses of certain opioids, which the companies are not allowed to do themselves.
7 This had the effect of further broadening the categories of medical conditions for which
8 physicians were encouraged to use opioids, particularly with respect to the use of opioids
9 for treatment of long-term chronic pain, such as back pain.

10 **Educational Materials:** Defendants also disseminated false assurances about the
11 safety and efficacy of opioids through “patient education” brochures and websites. The
12 materials often were edited by KOLs with extensive financial ties to the Defendants (paid
13 speaker positions, grants, etc.).

14 **CME:** Another vehicle by which Defendants communicated their misleading
15 messaging about opioids was through sponsoring continuing medical education (CME)
16 activities. The CMEs were used to spread Defendants’ messaging as to opioids generally,
17 not just the specific products they sold. Some Defendants created “captive” CME
18 programs that, in theory, were run by independent sponsors, but in fact were funded
19 entirely by one or more opioid manufacturers, who both the steered the content and
20 faculty for the programs (often the same physicians who were paid KOLs for the
21 companies), used sales representatives to invite doctors to the events, and then had sales
22 representatives attend the events. While there is nothing inherently wrong with industry-
23 sponsored CME, the CMEs at issue here were carefully managed by the sales marketing
24 and other commercial departments of the Defendants and were not independent, “hands
25 off” or viewpoint-neutral.

26 **Front Groups:** In a similar vein, Defendants provided financial support to a wide
27 variety of “front groups” that maintained the appearance of independence and legitimacy,
28 but advanced Defendants’ false messaging about opioids, including through treatment

1 guidelines, journal articles, and conferences. As with the CME-related activity, the
2 financial support Defendants gave to these front groups was provided with the expectation
3 that the groups receiving support would convey pro-opioid messaging consistent with the
4 companies' objectives. Indeed, Defendants were able to control the messages, including
5 sponsoring particular publications or brochures with pro-opioid content approved by
6 Defendants. A 2020 report issued by the United States Senate Finance Committee details
7 its findings about the relationship between opioid manufacturers and a variety of front
8 groups who advanced pro-opioid messaging. The report states that "the Committee is
9 releasing the financial information collected during the 2012 investigation, in addition to
10 data collected over the past two years, because we remain concerned that the opioid
11 epidemic was driven, in part, by misinformation and dubious marketing practices used by
12 pharmaceutical companies and the tax-exempt groups they fund."

13 Defendants used these channels to deliver their misrepresentations about opioids in
14 both branded and unbranded contexts. Some misleading statements were made in the
15 form of promotion of specific branded drugs; other misleading statements pertained to
16 prescription opioids generally and served to reassure doctors about the purported safety of
17 opioid therapy without reference to particular products. Importantly, for Defendants who
18 manufacture both branded and generic opioids, there is a synergy between these two types
19 of promotional activity. Defendants understood that promotion of their branded products
20 would also increase the market for their generic drugs, while unbranded materials that
21 reassured doctors about opioids generally would increase the market for all opioids,
22 including both branded and generic drugs. Indeed, many of the most insidious
23 misrepresentations were made in the context of unbranded materials that served to
24 promote opioids generally and often did not even appear to be promotional materials.
25 Thus, while Defendants attempt to draw a bright line between their branded and
26 unbranded promotional activities, the reality is that they reaped the benefit of all of their
27 misleading marketing activities across all of their opioid products.

28 Moreover, Defendants' improper promotion of opioids was not limited to false and

misleading claims about the risks and benefits, but also included the use of unfair and improper tactics for promoting the use of a controlled substance. These tactics included incentive-based compensation programs for their sales representatives and their managers, including bonuses and contests for those representatives who could “sell” the most opioids. Defendants’ campaign to turn dangerous, addictive drugs into “blockbuster” best-sellers was itself an unfair and improper tactic, given the dangerous nature of the product in question. Defendants also used data on opioid prescriptions to identify and target high volume prescribers for marketing purposes, but failed to use that same data to comply with their anti-diversion obligations under the CSA. This conduct contributed to the oversupply of opioids in San Francisco and the resulting public nuisance, and also constituted an unfair business practice in violation of the UCL.

2. *Walgreens’ Participation in the False and Misleading Statements*

Defendant Walgreen Co. (“Walgreens”) occupies a critical position in the opioid supply chain and, accordingly, in this litigation. In addition to its role in the distribution and dispensing of prescription opioids (discussed below), Walgreens collaborated with Defendants to: (1) promote the widespread availability of opioids, including through “Super Stores” and increased inventory in its 24-hour stores; (2) spread pro-opioids misinformation to its pharmacists; and (3) engage in direct-to-patient advertising of opioids in Walgreens’ pharmacies.

As part of its efforts to promote the availability of opioids, Walgreens proposed increased stocking of opioids in its 24-hour stores, multiplying opioid inventory as much as eight-fold to cover each area, and assuring high prescribers that Walgreens stores had adequate supply. Walgreens also discussed providing doctors the assurance that prescriptions for opioids would be filled by pharmacists less likely to question their prescribing.

Walgreens worked with various manufacturers on continuing-education programs for pharmacists and agreed to distribute “Manufacturer Product Updates” (MPUs) about opioids products in exchange for payment. These MPUs were another means by which the

1 manufacturers spread false and misleading messaging about their opioid products. By
2 providing such messages to its pharmacists, Walgreens improperly encouraged them to
3 underestimate the significant risks of opioids, which had the natural and foreseeable result
4 of reducing the level of scrutiny that Walgreens' pharmacy employees applied to opioid
5 prescriptions.

6 3. *The Causal Link between Defendants' Conduct and the Increase in*
7 *Inappropriate Prescribing*

8 Internal company documents show that the connection between Defendants'
9 marketing efforts and increased sales was not merely theoretical. Rather, Defendants
10 were able to quantify a precise relationship between their marketing programs and sales
11 growth. They knew that marketing increased sales, and they knew by how much.

12 The net effect of the Defendants' pro-opioid messaging campaign was that
13 historically skeptical prescribers were led to believe that the so-called "new" opioids had
14 overcome the historical opioid-related problems about which they had learned in medical
15 school. This resulted in a paradigm shift in the way doctors thought about opioids, and
16 led to a massive increase in opioid prescribing.

17 But it wasn't simply an increase in the *number* of opioid prescriptions that
18 contributed to the opioid epidemic, it was a broadening of the conditions for which
19 opioids were prescribed, as well as increases in the dosages and durations for which
20 opioids were prescribed, along with a decrease in oversight as to who should receive
21 opioids and what level of supervision was required to ensure safe use. What the
22 Defendants accomplished was to bring about a wholesale paradigm shift in which the
23 entire understanding of when opioids are "medically appropriate" was altered. Doctors
24 came to believe that opioids were appropriate when an understanding of the true risks and
25 benefits of the drugs would have shown that they were not. This resulted in a dramatic
26 increase in the number of medically inappropriate opioid prescriptions that did not reflect
27 the true risks and benefits of the drugs. San Francisco was awash in opioids because
28 doctors had been led to believe that the drugs were much safer and more effective, as

1 compared to other therapies, than was in fact the case.

2 **E. Oversupply through Diversion**

3 The other significant source of excess opioids in San Francisco – and of significant
4 harms from those opioids – was diversion. Diversion refers to a situation in which opioids
5 make their way into the hands of someone other than a patient for whom they were
6 prescribed pursuant to a valid prescription. A valid prescription is one issued for a
7 legitimate medical purpose by an individual practitioner acting in the usual course of his
8 professional practice. (A “legitimate” medical purpose may nonetheless be a medically
9 inappropriate one – that is to say, the legitimacy of a prescription and its appropriateness
10 are entirely separate issues.) Opioids obtained through invalid prescriptions are, by
11 definition, diverted. Defendants contributed to a public nuisance in San Francisco by
12 failing to control the opioid supply chain and prevent diversion, when each of them was
13 under a legal obligation to provide effective controls against diversion of these drugs and
14 each of them had information in its possession that would have allowed them to detect and
15 stop at least some of the diversion that occurred.

16 *1. Regulatory Framework*

17 The prescription opioids that are the subject of these actions are regulated under the
18 federal CSA, 21 U.S.C. §§ 801, *et seq.*, a comprehensive statutory scheme enacted in
19 1970 to combat drug abuse. The purpose of the CSA was to establish a “closed system”
20 for the manufacture, distribution and sale of these exceptionally dangerous drugs to the
21 public and to control against the diversion of those drugs for non-medical use. *See* H.R.
22 Rep. 91-1444, 1970 U.S.C.C.A.N. 4566, 4571-72.

23 The CSA and its regulations categorize controlled substances into “schedules”
24 based on the degree of harm they pose to the community. 21 U.S.C. § 812. Schedule I
25 drugs, such as heroin, may not be prescribed or used for any purpose. Schedule II drugs
26 are tightly controlled and available only by prescription. Nearly all prescription opioids,
27 including oxycodone, hydrocodone, and hydromorphone, are currently categorized as
28 Schedule II drugs. Opioids used in combination with other drugs or that have a lower risk

1 for abuse and psychological or physical dependence are categorized as Schedule III (e.g.,
2 Codeine with aspirin), IV (e.g., Tramadol), or V (e.g., cough medicines that include
3 codeine). (Opioids are categorized in multiple ways, including, in particular, by their
4 relative strength as compared to morphine. That strength is expressed in “morphine
5 milligram equivalents” or MMEs. Drugs with lower MMEs are typically viewed as less
6 dangerous and may be scheduled less restrictively on that basis. Some opioids previously
7 thought to be less dangerous, and either left unscheduled or categorized on a less
8 restrictive schedule, have been scheduled or re-categorized once the true extent of their
9 dangers was understood.)

10 In order to ensure that controlled substances are handled, throughout the supply
11 chain, by those in the best position to maintain the closed system and prevent diversion,
12 the CSA requires anyone who manufactures, distributes, or dispenses controlled
13 substances to register with the Drug Enforcement Administration (“DEA”), the agency
14 charged with enforcement of the CSA. 21 U.S.C. § 822. It is unlawful for any person
15 knowingly to manufacture, distribute, or dispense controlled substances other than in
16 accordance with the requirements of the CSA and its implementing regulations. 21
17 U.S.C. § 841. The system requires that registered manufacturers sell only to registered
18 wholesale distributors (or registered dispensers) who sell only to registered dispensers,
19 who may dispense only to patients with valid prescriptions. Thus, in exchange for the
20 privilege of trading in these dangerous substances, registrants must comply with the
21 statutory and regulatory regime designed to protect individuals and communities from the
22 consequences of diversion use of these drugs. The CSA regulations require that all
23 registrants “provide effective controls and procedures to guard against theft and diversion
24 of controlled substances.” 21 C.F.R. § 1301.71(a).

25 Distributors of controlled substances – which includes manufacturers when they
26 sell to wholesalers as well as wholesalers who sell to dispensers – are required to maintain
27 a system for detecting and reporting suspicious orders and must halt shipments of orders
28 so identified until it can be determined that the orders are proper and not part of a

1 diversion scheme. 21 C.F.R. § 1301.71(a), § 1301.74; *City and Cty. of San Francisco v.*
 2 *Purdue Pharma LP*, 491 F. Supp. 3d 610, 631 (N.D. Ca. Sept. 30, 2020) (“*San Francisco*
 3 *MTD*”); *In re Nat’l Prescription Opiate Litig.*, No. 1:17-MD-2804, 2019 WL 3917575, at
 4 *1 (N.D. Ohio Aug. 19, 2019).

5 With respect to dispensing, the CSA provides that, unless dispensed directly by a
 6 non-pharmacist practitioner, no Schedule II controlled substance may be dispensed
 7 without the written prescription of a practitioner, such as a physician, except in an
 8 emergency, and no Schedule III controlled substance may be dispensed without a written
 9 or oral prescription. 21 U.S.C. § 829(a)-(b). The implementing regulations regarding
 10 dispensing of controlled substances specify that a valid controlled substance prescription
 11 may only be issued by an individual who is authorized to prescribe and is registered with
 12 the DEA. 21 U.S.C. § 822; 21 C.F.R. § 1306.03. Furthermore, a prescription, whether
 13 written or oral, is legally valid only if it is issued for “a legitimate medical purpose by an
 14 individual practitioner acting in the usual course of his [or her] professional practice.” 21
 15 C.F.R. § 1306.04(a); *see also San Francisco MTD*, 491 F. Supp. 3d at 669.

16 2. *What the People’s Evidence Will Show*

17 None of the Defendants complied with their obligations under the CSA to maintain
 18 effective controls against diversion. Each Defendant failed to establish, implement, or
 19 follow effective systems to detect and control against diversion, and often did not have
 20 any system at all. Moreover, each of the Defendants was in possession of enormous
 21 amounts of data that would have alerted it to the possibility of diversion, but failed to
 22 make appropriate use of data (which were used to increase profits) to detect and
 23 investigate potential diversion.

24 (a) Manufacturers (Teva, Allergan, Endo)

25 For the most part, the Manufacturer Defendants did not sell directly to dispensers
 26 (such as pharmacies), but to intermediaries that then distributed to dispensers.
 27 Nonetheless, the Manufacturers had a wealth of information about their “downstream
 28 customers” – that is, the customers of their customers – to see which doctors wrote

1 prescriptions for their products and which dispensers filled those prescriptions.

2 First, as part of their sales and marketing operations, Defendants routinely bought
3 or licensed detailed data and reports from companies like IMS/IQVIA, Wolters-Kluwer,
4 and ValueCentric that gave a reliable picture of how many prescriptions of which types of
5 opioids each practitioner was writing. This granular data was used to target sales efforts
6 and track the effectiveness of the Defendants' sales and marketing efforts, including to
7 compensate the salesforce. Defendants also tracked opioid stocking and "pull through" at
8 the pharmacies. And, of course, sales people calling on doctors and pharmacies had
9 information about what they were seeing and hearing in the field, including first-hand
10 observation of "pill mills" in their territories.

11 Second, Defendants also had so-called "chargeback" data, provided by the
12 wholesalers. The "chargeback" data allowed Defendants to track with precision which
13 opioids were sold by which wholesalers in what volumes and to which pharmacies.
14 Defendants routinely used this "chargeback" data as part of programs that allowed
15 wholesalers to claim credits for discounted pricing Defendants agreed to with certain
16 dispensers. All three of the Manufacturer Defendant families – Teva, Endo, and Allergan
17 – were in possession of such "chargeback" and other dispensing sales data.

18 All of this data and information shows the volume of prescriptions filled at
19 particular pharmacies and written by particular doctors and thus provides a window into
20 unusual increases in the volume of opioid prescriptions in particular places, as well as
21 unusual patterns of prescribing, including particular suspicious drugs combinations. Such
22 patterns may be indicative of diversion. See 21 C.F.R. § 1301.74 (defining "suspicious
23 orders" to include "orders of unusual size, orders deviating substantially from a normal
24 pattern, and orders of unusual frequency"). This data was sufficient for Manufacturers to
25 create an indirect suspicious order management (SOM) program from which they could
26 track unusual patterns, volume, or frequency of opioid dispensing at particular
27 pharmacies. In each instance, the Manufacturers knew which pharmacies were selling
28 unusual or suspicious amounts of opioids: they had a window into the likely places where

1 diversion was occurring.

2 None of the Manufacturers, however, implemented or maintained for any
3 significant period such a system. They failed to maintain appropriate systems for
4 detecting suspicious orders at any level, and failed, in particular, to make use of the data
5 that told them what was actually happening at the pharmacies where their drugs were
6 being sold. Each of them was told by the DEA what they needed to do and each of them
7 hired consultants who told them that their systems were inadequate. All of them ignored
8 the criticisms of their consultants and failed to implement effective controls against
9 diversion making use of the data in their possession.

10 The failures of the Manufacturers to make use of their data and implement
11 effective SOM programs led to the shipment and dispensing of large amounts of opioids
12 that were suspicious and should have been investigated. As discussed below, this
13 evidence is sufficient for the Court, acting as factfinder, to find that the failures of the
14 Manufacturers to maintain effective controls against diversion led to diversion and its
15 associated harms in San Francisco.

16 (b) Distributors (Walgreens and Anda)

17 Through 2014, Walgreens served as a wholesale distributor of opioids to its retail
18 stores. Anda was a wholesale distributor of opioids from at least 2000 through the
19 present. During these time frames, the Controlled Substances Act imposed a duty on
20 Walgreens and Anda—as wholesalers—to design and implement suspicious order
21 monitoring systems to identify controlled substances distribution orders that unusually
22 large or frequent or otherwise deviated from normal patterns. Walgreens and Anda were
23 obligated to report suspicious orders to the DEA when it discovered them, conduct
24 independent investigations prior to filling them, and then ship to their stores or customers
25 only if the investigation cleared the suspicion. In 2006 and 2007, the Deputy Assistant
26 Administrator of the DEA’s Office of Diversion Control, Joseph Rannazzisi, sent letters to
27 DEA registrants reiterating their legal duties to “design and operate a system to disclose
28 . . . suspicious orders of controlled substances.” The letters also emphasized the

1 requirement to report suspicious orders to the DEA and the prohibition against shipping
2 any order flagged as suspicious until due diligence is performed on the order and the
3 suspicion is cleared.

4 Despite these duties and reminders, until 2012, Walgreens maintained no bona fide
5 suspicious order monitoring system. In 2006, DEA informed Walgreens it was not
6 satisfying CSA and DEA requirements. Walgreens' internal audits from 2008-2012 admit
7 that "there was no monitoring process in place to stop a suspicious order to assess if the
8 order is suspicious or not" and that Walgreens was "filling orders that have been deemed
9 suspicious without performing any research to ascertain their legitimacy" and could be
10 filling "illicit orders." In 2010, its Divisional Supply Chain VP wrote, "We were
11 instructed in 1985 not to review or contact anyone on the data. Who . . . has been
12 reviewing the data collected for the past twenty-five year?" Instead of reviewing
13 suspicious orders, conducting due diligence where required, and reporting them to the
14 DEA before shipment, Walgreens was simply listing orders that exceeded an
15 inappropriate "3 times" threshold (which the DEA had rejected), filling all such orders,
16 and sending lists of the orders to the DEA after they were shipped. Walgreens did not
17 disclose to the DEA that Walgreens had not performed due diligence on the suspicious
18 orders or cleared the suspicions before shipment, as required by the CSA.

19 Although Walgreens worked to improve its systems in 2012 by creating its
20 Pharmaceutical Integrity division, at the same time it faced regulatory action by the DEA
21 over gross violations of its duties and responsibilities vis-à-vis suspicious order
22 monitoring and controlled substance dispensing, as will be further discussed below.
23 Walgreens ultimately entered into a settlement with the DEA in 2013 in which it admitted
24 that "suspicious order reporting for distribution to certain pharmacies did not meet the
25 standards identified by the DEA." Walgreens then exited the business of opioid
26 distribution.

27 As a result of its failure to maintain a system of compliance, Walgreens repeatedly
28 shipped suspicious orders of prescription opioids to its pharmacies without any due

1 diligence review. Walgreens admitted as much in internal audits; it also admitted the
2 same to the DEA in its 2013 settlement. Walgreens' own suspicious order reports show
3 that the size of the orders it was shipping to its San Francisco stores were multiplying over
4 time. The scale of the increases was not justifiable and shows that Walgreens was not
5 reviewing its data. The escalating orders would—at a minimum—have required
6 significant due diligence to determine whether and where diversion was occurring.

7 For its part, Anda also failed to conduct adequate due diligence for its opioids
8 customers, and failed to design and implement a suspicious order monitoring program to
9 prevent diversion. Anda also designed its processes to circumvent and conceal, rather
10 than report, the suspicious orders placed by its customers.

11 In 2005, and again in 2007, the DEA identified Anda as the primary hydrocodone
12 supplier to internet pharmacies. From at least 2000 until 2010, Anda supplied opioids to a
13 number of other repackagers and distributors at abnormally high levels or, in some
14 instances, on an “unlimited” basis. Several of these distributors and repackagers, in turn,
15 channeled opioids into physicians' offices and clinics in San Francisco. Anda was a
16 significant opioid supply source to both Southwood Pharmaceuticals and the Harvard
17 Drug Group, both of which had their licenses suspended by the DEA.

18 Between 2005 and August 2007, Anda identified thousands of suspicious orders,
19 reported them to the DEA, but still shipped them to customers in violation of the CSA.
20 Starting in approximately September 2007, Anda discontinued its practice of reporting
21 suspicious orders to the DEA and has failed to appropriately identify and report suspicious
22 orders ever since. After identifying thousands of orders as suspicious and reporting them
23 to the DEA between 2005 and August 2007, Anda failed to subsequently report suspicious
24 orders anywhere in the country for almost eight years.

25 Anda designed its opioids ordering processes to either conceal or destroy evidence
26 of suspicious orders. Anda's electronic ordering system was designed *not* to record orders
27 that were deemed as excessive so that there was no suspicious order to report. In other
28 instances, even when orders were identified as suspicious by Anda, Anda compliance

1 personnel would simply “delete” the orders rather than report them to the DEA.

2 (c) Walgreens as Dispenser

3 Walgreens’ obligations as a dispenser are described above. The CSA and
4 California standards of pharmacy practice both impose obligations on pharmacies and
5 pharmacists to investigate so-called “red-flag” prescriptions to ensure they are valid.
6 Because registered manufacturers sell to registered distributors who sell to registered
7 dispensers, in the end, the only means for prescription opioids to “escape” from the closed
8 system are through theft or through dispensing pursuant to a prescription. Dispensing is
9 where a huge proportion of diversion “leaks” occur. Thus, if all other checks within the
10 system fail, the pharmacy is supposed to serve as the last line of defense.

11 As the largest retail pharmacy by market share in San Francisco (56% of opioids
12 from 2012-2020), Walgreens was in a unique position to serve as a gatekeeper against
13 diversion—and that means investigating each red flag of diversion evidenced at the
14 presentation of a prescription and documenting the resolution of that red flag prior to
15 dispensing the medication. Yet, for many years, the policy and practice at Walgreens was
16 to dispense virtually every prescription as long as the prescriber “said it was ok.” Then, in
17 2011 and 2013, Walgreens settled DEA enforcement actions based on conduct in
18 California and Florida (but implicating nationwide practices) that exposed Walgreens’
19 failures under the CSA. As a result of those settlements, Walgreens began to pay lip-
20 service to the need to guard against diversion by revising its policies, but it failed to
21 meaningfully implement the systems that would have prevented diversion. For example,
22 Walgreens implemented a due diligence checklist, but it only mandated its use for three
23 specific, single-ingredient opioids and excluded highly prescribed and highly abused
24 hydrocodone products. Rather than take its duties under the CSA seriously, Walgreens’
25 head of controlled substance compliance suggested that the company simply “consider not
26 documenting our own potential noncompliance.”

27 Walgreens also maintained vast amounts of data about the prescriptions it filled
28 and the patients who filled them, but failed to use this data to aid in the identification of

1 “red-flag” prescriptions or suspicious prescribers. To the extent that Walgreens did
2 analyze its data to identify prescriptions with indicia of diversion, it kept that information
3 from its pharmacists and did not provide them a systematic means of sharing concerns
4 about suspicious prescriptions and prescribers with other pharmacists within the chain.
5 Nor did it ever ban suspicious prescribers from their access to the chain. Instead, diligent
6 Walgreens pharmacists within the chain kept critical information about suspicious
7 prescribers on Post-it notes; could not circulate information about warnings,
8 investigations, or bans between stores; and never received information from the company
9 that would have reduced the volume of suspicious prescriptions that were improperly
10 filled. Walgreens also kept important records that could assist the next pharmacist—e.g.,
11 refusal-to-fill forms—in hard copy and inaccessible to its personnel. Walgreens had the
12 information necessary to see patterns of diversion—it just didn’t want its pharmacists to
13 see it. As a result, San Francisco Walgreens filled an alarming number of opioid
14 prescriptions from doctors with extremely suspicious prescribing patterns, many of whose
15 licenses were revoked for gross negligence.

16 Other policies ensured that even pharmacists who wished to investigate suspicious
17 prescriptions would find it difficult to do so. Walgreens instituted performance metrics
18 that focused on speed, prescription volume, and customer feedback. This meant that
19 pharmacists often did not have the ability to conduct adequate prescription due diligence
20 if they wished to keep their jobs. Pharmacists were consistently subject to extreme
21 workloads that put patient safety at risk, as documented in an internal report and by
22 Walgreens’ pharmacists in numerous internal complaints. Walgreens, and the pharmacists
23 who worked in its pharmacies, were well aware that a customer lost because Walgreens
24 refused to fill his or her opioid prescription might be an entire patient “profile” lost and all
25 the revenue that comes with it—e.g., medications for blood pressure, cholesterol, diabetes,
26 etc. Walgreens was also well aware that chronic pain patients represented a significant
27 percentage of its business and especially did not want such patients to take their business
28 elsewhere. As documented in internal complaints and pharmacist testimony, this led

1 managers to put pressure on pharmacists to disregard Walgreens’ written dispensing
2 policies (as revamped in 2012 in the midst of DEA enforcement actions) and to prioritize
3 profits over patient safety.

4 (d) Causation

5 Defendants’ failure to maintain effective controls against diversion led to diversion
6 and also contributed to the public nuisance created by the illicit oversupply of prescription
7 opioids. The influx of suspicious opioid orders into San Francisco as a result of lax anti-
8 diversion policies is precisely the result Congress set out to avoid when it enacted the
9 CSA, and when DEA adopted its implementing regulations. As a 2007 letter from DEA
10 to Defendants states: “even just one distributor that uses its DEA registration to facilitate
11 diversion can cause enormous harm.” And, as this Court itself observed in rejecting
12 Defendants’ motion to dismiss, “[t]he very existence of the duties to maintain effective
13 controls supports the notion that opioid misuse is foreseeable.” *San Francisco MTD*, 491
14 F. Supp. 3d at 680. Moreover, the People’s summary judgment evidence shows that
15 controls against diversion – if used – would have worked. For example, when Walgreens
16 implemented a more robust suspicious order system in 2013, its sales of OxyContin
17 dropped 18% in three months with a disproportionate share of the reduction occurring in
18 higher dosages (i.e., the most dangerous pills).

19 Defendants failed to identify, halt and investigate hundreds of thousands of
20 suspicious orders with indicia that diversion might be occurring, and dispensed well over
21 a million prescriptions in San Francisco that had red flags indicative of potential
22 diversion.

23 In particular, the People’s expert, Dr. Craig McCann, analyzed data from the
24 DEA’s Automation of Reports and Consolidated Orders System (ARCOS) under multiple
25 algorithms that have been used to determine the volume of suspicious orders shipped by
26 Walgreens to its stores and by Anda to its customers. This data shows that, for both
27 Walgreens and Anda, significant percentages of oxycodone and hydrocodone orders
28 should have been flagged as suspicious and not shipped unless the distributors’ due

1 diligence eliminated the suspicion of diversion. Dr. McCann also analyzed which
2 manufacturer's opioid products were shipped to pharmacies in San Francisco. He applied
3 metrics indicative of suspicious orders to the total quantities shipped by wholesalers of
4 each manufacturer's products, with the understanding that the manufacturers had access to
5 the data demonstrating the extent to which the sales of their products were suggestive of
6 ongoing diversion. According to the People's expert, James Rafalski, this analysis, along
7 with the absence of adequate distributor due diligence, showed that tens, if not hundreds,
8 of thousands, of Defendants' products were shipped to San Francisco in transactions that,
9 alone or in the aggregate, should have alerted Defendants to the dangers of diversion. As
10 Rafalski makes clear, the evidence supports the inference that the Defendants' failure to
11 identify and halt suspicious orders led to large quantities of suspicious opioids entering
12 San Francisco and, predictably, to diversion of significant quantities of them.

13 The evidence also shows the effect of Walgreens' failure to comply with the CSA
14 at the dispensing level. The People's expert, Carmen Catizone, has identified specific
15 indicia of potential diversion that may be evidenced by an opioid prescription. Applying
16 algorithms that reflect these red flags, Dr. McCann has analyzed Walgreens' dispensing
17 data; that analysis shows that approximately *60% of the opioid prescriptions that*
18 *Walgreens filled* presented with at least one red flag of diversion. Another of the People's
19 experts, Elizabeth Park, analyzed Walgreens' due diligence notes and concludes that, at
20 least 95% of the time, Walgreens' pharmacists did not identify and document resolution of
21 red flags prior to dispensing opioids, meaning that the vast majority of suspicious
22 prescriptions were simply dispensed in the face of easily-identifiable concerns that should
23 have been recognized and investigated. Notably, Walgreens' policy required pharmacists
24 to document any due diligence efforts, which supports the general pharmacy principle and
25 California Board of Pharmacy expectation that "if you don't document it, it didn't
26 happen."

27 Among these filled prescriptions, there were many written by suspicious
28 prescribers who were subject to discipline for drug diversion and thus whose prescriptions

1 were very likely to be diverted. In some instances, Walgreens learned about these
 2 suspicious prescribers but continued filling for them until the last possible moment.

3 The precise consequence anticipated and foreseen by Congress and the DEA of the
 4 failure to maintain effective control – widespread diversion of prescription opioids –
 5 occurred in San Francisco. As Judge Polster has explained, this kind of evidence is
 6 sufficient to establish causation. *See In re Nat'l Prescription Opiate Litig.*, 2019 WL
 7 4178617, at *3. In particular, in the face of evidence of the massive increase of
 8 prescription opioids being sold in San Francisco, and evidence that there was a complete
 9 failure by the Defendants to maintain effective controls against diversion, the factfinder
 10 and should reasonably infer that these failures were a substantial factor in producing the
 11 harm demonstrated by the People in this case.

12 **III. PROPOSED CONCLUSIONS OF LAW**

13 **A. The People Have Proven Their Public Nuisance Cause of Action**

14 1. To prove a cause of action for public nuisance under California law, the
 15 People must show that a defendant (1) despite having knowledge of the hazards (2)
 16 engaged in affirmative conduct (3) that was a substantial factor (4) in creating or
 17 maintaining an unreasonable and substantial interference with one or more rights common
 18 to the public. *People ex rel. Gallo v. Acuna*, 929 P.2d 596, 604, 618 (Cal. 1997); *People*
 19 *v. ConAgra Grocery Prods.*, 227 Cal. Rptr. 3d 499, 525 (Ct. App. 2017); *Cty. of Santa*
 20 *Clara v. Atlantic Richfield Co.*, 40 Cal. Rptr. 3d 313, 325 (Ct. App. 2006).

21 2. The burden of proof in a public nuisance action is a preponderance of the
 22 evidence. *People v. Frangadakis*, 7 Cal. Rptr. 776, 782 (Ct. App. 1960) (“This being a
 23 case in equity, the burden of the People was to prove the case only by a preponderance of
 24 the evidence.”).

25 3. There is no statute of limitations for a public nuisance cause of action when
 26 the nuisance continues to exist. Civ. Code § 3490 (“No lapse of time can legalize a public
 27 nuisance, amounting to an actual obstruction of public right.”); *Mangini v. Aerojet-*
 28 *General Corp.*, 281 Cal. Rptr. 827, 838 (Ct. App. 1991) (“Section 3490 has been

1 construed to mean that the statute of limitations is no defense to an action brought by a
2 public entity to abate a public nuisance.”).

3 4. The People have proven their public nuisance claim by a preponderance of
4 the evidence.

5 1. *An Opioid Crisis Exists in San Francisco and Constitutes a Public
6 Nuisance*

7 5. A nuisance is “[a]nything” that is “injurious to health” or “interfere[s] with
8 the comfortable enjoyment of life or property.” Civ. Code § 3479; *San Francisco MTD*,
9 491 F. Supp. 3d at 669.

10 6. A public nuisance is one that “affects at the same time any entire
11 community or neighborhood, or any considerable number of persons.” Civ. Code § 3480;
12 *San Francisco MTD*, 491 F. Supp. 3d at 669.

13 7. Public nuisances at common law are defined as “‘offenses against, or
14 interferences with, the exercise of *rights common to the public*,’ such as public health,
15 safety, peace, comfort, or convenience.” *Citizens for Odor Nuisance Abatement v. City of*
16 *San Diego* 213 Cal. Rptr. 3d 538, 545 (Ct. App. 2017) (quoting *Acuna*, 929 P.2d at 604).
17 The interference “must be both substantial and unreasonable.” *Acuna*, 929 P.2d at 604.
18 The interference is substantial if it causes “significant harm.” *Id.* at 605. The interference
19 is “unreasonable” if “the gravity of the harm outweighs the social utility of the
20 defendant’s conduct.” *San Diego Gas & Electric Co. v. Superior Court*, 920 P.2d 669, 697
21 (Cal. 1996).

22 8. The Restatement (Second) of Torts lists three circumstances that qualify as
23 “unreasonable”: (a) whether the conduct involves a significant interference with the public
24 health, the public safety, the public peace, the public comfort, or the public convenience;
25 (b) whether the conduct is proscribed by a statute, ordinance, or administrative regulation,
26 or (c) whether the conduct is of a continuing nature or has produced permanent or long-
27 lasting effect and, as the actor knows or has reason to know, has a significant effect upon
28 the public right. Restatement (Second) of Torts § 821B(2).

1 9. The evidence shows the existence of an opioid crisis constituting a public
2 nuisance in San Francisco. This opioid crisis encompasses the significant increase in the
3 availability and strength of prescription opioids in San Francisco together with the
4 accompanying rise in opioid addiction, abuse, misuse, opioid-related morbidity, diversion,
5 overdoses, and deaths that have followed. The opioid crisis affects a considerable number
6 of people in San Francisco. It is not limited to individuals suffering from addiction, but
7 include harm to entire communities. The evidence shows, for example, that opioid use
8 disorder (OUD) is an all-encompassing and often lifelong disease that in turn exacerbates
9 or creates other medical conditions, increases the risk of illicit drug use and the
10 accompanying harms of such use, heightens the risk of a non-fatal or fatal overdoses,
11 imposes tremendous costs on healthcare, mental healthcare, and first responder systems,
12 and often requires sustained and prolonged treatment and services for the individual and
13 their families.

14 10. The opioid crisis in San Francisco constitutes a substantial interference with
15 public health and other public rights. As described above, the opioid crisis has inflicted
16 significant harm within San Francisco in terms of the number of people affected by OUD,
17 the profound suffering they and those in their community experience, and the resulting
18 consequences and demands on the healthcare system and other service needs in San
19 Francisco.

20 11. The opioid crisis in San Francisco also constitutes an unreasonable
21 interference with the common right to public health and other public rights. Defendants'
22 wrongful conduct meets each of the possible definitions of "unreasonable" in the
23 Restatement and California case law. Manufacturing Defendants' affirmative and
24 deceptive promotion of opioids, despite their knowledge of the harms that would result,
25 caused harm that far outweighed any possible social utility: While prescription opioids
26 have certain legitimate medical uses consistent with their respective FDA approvals,
27 promoting these highly addictive drugs in a manner that downplays and/or omits their
28 risks and overstates their benefits has no social utility, and certainly none that would

1 outweigh the grave harms inflicted on the People in San Francisco. This marketing
 2 misconduct also is unreasonable under the Restatement because it had a significant
 3 adverse effect on public health and other public rights, and that adverse effect has been
 4 long-lasting.

5 12. Likewise, all Defendants' failure to design and operate systems to identify
 6 suspicious orders of prescription opioids, maintain effective controls against diversion,
 7 and halt distribution and dispensing of suspicious orders, thereby contributing to the
 8 oversupply of such drugs and fueling an illegal secondary market, constitutes an
 9 unreasonable interference with the common right to public health and other public rights.
 10 Failure to take these actions served no social utility, and caused a significant adverse
 11 effect on public health and other public rights that has been long-lasting. Moreover, this
 12 conduct is proscribed by the CSA and its implementing regulations.

13 2. *Each Defendant Engaged in Conduct that Contributed to a Public*
 14 *Nuisance in San Francisco*

15 13. To establish liability for a public nuisance, a plaintiff may prove that a
 16 defendant "created or assisted in the creation" of a public nuisance, generally through
 17 some "affirmative steps." *Cty. of Santa Clara*, 40 Cal. Rptr. 3d at 325; *City of Modesto*
 18 *Redevelopment Agency v. Superior Court*, 13 Cal. Rptr. 3d 865, 876 (Ct. App. 2004).
 19 "Public nuisance liability 'does not hinge on whether the defendant owns, possesses, or
 20 controls the property, nor on whether he is in a position to abate the nuisance; the critical
 21 question is whether the defendant created to assisted in the creation of the nuisance.'" *Melton v. Boustred*, 107 Cal. Rptr. 3d 481, 499 (Ct. App. 2010) (quoting *City of Modesto*
 22 *Redevelopment Agency*, 13 Cal. Rptr. 3d at 872). A defendant is likewise liable for
 23 maintaining or assisting in the maintenance of a public nuisance. *See Acuna*, 929 P.2d at
 24 618.

25 14. A manufacturer may be liable for a public nuisance if it affirmatively
 26 promoted a product for a use that the manufacturer knew to be hazardous. *ConAgra*, 227
 27 Cal. Rptr. 3d at 529–30. Proof of fraudulent conduct is not required. *Cty. of Santa Clara*,
 28

1 40 Cal. Rptr. 3d at 328–29; *City of Modesto Redevelopment Agency*, 13 Cal. Rptr. 3d at
 2 872–73, 876.

3 15. Defendants may also be liable for contributing to a public nuisance where
 4 they “participate[]” in affirmative, third-party conduct that was a substantial factor in
 5 bringing about the nuisance. *ConAgra*, 227 Cal. Rptr. 3d at 543. For purposes of a public
 6 nuisance cause of action, financial support of third-party conduct is sufficient to
 7 demonstrate that Defendants “participated” in that conduct. *See id.* at 536–38, 543–44
 8 (third party promotional activities were attributed to the defendants where they provided
 9 financial support for advertisements and promotional campaigns placed by paint and
 10 hardware stores and by trade associations in which they were members).

11 16. California authorities disagree about whether a plaintiff must prove that a
 12 defendant acted with “actual knowledge” of the hazard to public health and other public
 13 rights that would result from its conduct. *San Francisco MTD*, 491 F. Supp. 3d at 672–
 14 674. However, to demonstrate actual knowledge, the People do not need to show that
 15 Defendants knew of the specific nuisance occurring in San Francisco. Instead, the People
 16 must only show that Defendants had actual knowledge of the risks associated with opioids
 17 that, taken together, resulted in the public nuisance. *ConAgra*, 227 Cal. Rptr. 3d at 530
 18 (actual knowledge established where defendants knew that “(1) ‘lower level lead exposure
 19 harmed children,’ (2) ‘lead paint used on the interiors of homes would deteriorate,’ and
 20 (3) ‘lead dust resulting from this deterioration would poison children and cause serious
 21 injury.’”).

22 17. Actual knowledge may be shown exclusively through circumstantial
 23 evidence and reasonable inferences from the circumstantial evidence. *Id.* (above facts
 24 were sufficient to show that lead paint manufacturers “*must have known . . . that interior*
 25 *lead paint posed a serious risk of harm to children*”).

26 18. This Court need not decide whether California law requires proof of actual
 27 knowledge, because the People have shown by a preponderance of the evidence that each
 28 Defendant actually knew of the risks associated with prescription opioids, including the

1 risk of opioid addiction, misuse, abuse, diversion, overdose, and death, and that increasing
 2 the availability of prescription opioids, and or failing to prevent their diversion, would
 3 lead—and in fact was leading—to an increase in these adverse public health harms.

4 3. *Defendants’ Conduct, Individually and Collectively, Caused the*
 5 *Public Nuisance Existing in San Francisco.*

6 19. The People’s evidence establishes by a preponderance of the evidence that
 7 each Defendant’s conduct is a cause in fact and a proximate cause of the public nuisance
 8 existing in San Francisco.

9 (a) *Each Defendant’s Conduct Was a Substantial Factor in*
 10 *Bringing About a Public Nuisance in the Jurisdictions*

11 20. In order to establish causation for a public nuisance, the People need only
 12 show that a Defendant’s conduct was “a substantial factor” in bringing about the public
 13 nuisance. *ConAgra*, 227 Cal. Rptr. 3d at 543; *see also San Francisco MTD*, 491 F. Supp.
 14 3d at 677.

15 21. “The substantial factor standard is a relatively broad one, requiring only that
 16 the contribution of the individual cause be more than negligible or theoretical. Thus, a
 17 force which plays only an ‘infinitesimal’ or ‘theoretical’ part in bringing about injury,
 18 damage, or loss is not a substantial factor, but a very minor force that does cause harm is a
 19 substantial factor.” *ConAgra*, 227 Cal. Rptr. 3d at 543 (citations and quotation marks
 20 omitted); *see also Bockrath v. Aldrich Chemical Co., Inc.*, 980 P.2d 398, 403–04 (Cal.
 21 1999). The substantial factor standard is broader than “but for” causation and reaches
 22 situations “involving independent or concurrent causes in fact.” *Rutherford v. Owens-*
 23 *Illinois, Inc.*, 941 P.2d 1203, 1214 (Cal. 1997) (“[T]he substantial factor standard [was]
 24 formulated to aid plaintiffs as a broader rule of causality than the ‘but for’ test . . .”).

25 22. If a defendant’s wrongful conduct “operated concurrently with other
 26 contemporaneous forces to produce the harm, it is a substantial factor, and thus a legal
 27 cause, if the injury, or its full extent, would not have occurred but for that conduct.” *In re*
 28 *Ethan C.*, 279 P.3d 1052, 1071 (Cal. 2012). Thus, the People only had to demonstrate that
 “Manufacturers’ and Distributors’ conduct was necessary in bringing about the *full extent*

1 of the [People's] injuries.” *San Francisco MTD*, 491 F. Supp. 3d at 677. The People have
2 satisfied this burden.

3 23. The People have proven by a preponderance of the evidence that each
4 Defendant was a substantial factor in bringing about the opioid crisis in San Francisco:
5 each Defendant contributed to an increase in the availability and strength of prescription
6 opioids that triggered the present crisis of opioid misuse, abuse, addiction, diversion,
7 overdose, and death that exists in San Francisco.

8 24. As this Court found above, each of the Manufacturing Defendant's
9 marketing and promotion was a substantial factor in expanding the overall market for
10 prescription opioids, including in San Francisco. This includes through unbranded
11 marketing, which promoted the use of prescription opioids as a class, not any particular
12 branded or generic product, and thus expands the market as a whole. It also includes
13 branded marketing, which, in addition to promoting the specific product marketed, also
14 expands the market for the same Defendant's other branded and generic opioids. As such,
15 the evidence shows that Defendants' marketing was effective at increasing the number of
16 prescriptions for opioids and the strength of those prescriptions (as expressed in morphine
17 milligram equivalents or MMEs) in San Francisco.

18 25. The increase in the supply and strength of opioids, including Defendants'
19 branded and generic opioids, in San Francisco created a concomitant rise in addiction,
20 misuse, abuse, diversion, overdose, and death that constitutes the opioid crisis in San
21 Francisco.

22 26. Similarly, the evidence has shown that all Defendants' failure to design and
23 operate systems to identify suspicious orders of prescription opioids, failure to maintain
24 effective controls against diversion, and failure to halt distribution and dispensing of
25 suspicious orders were substantial factors in bringing about the opioid crisis in San
26 Francisco. Defendants' failure to maintain such controls, as required by the CSA, fueled
27 the oversupply of pills into San Francisco, and the growth of an illegal secondary market
28

1 in both diverted and unlawful opioids, and significantly contributed to rising addiction and
2 overdose rates in San Francisco.

3 27. Each Defendant's misconduct was a substantial factor in bringing about the
4 opioid crisis as it exists in San Francisco today. Even though the number of prescriptions
5 has declined somewhat, the strength of those prescriptions remains higher than it was
6 before Defendants' marketing efforts. Moreover, as the People have shown, there
7 continue to be significant overdose deaths from prescription opioids and a large number of
8 the people in San Francisco who continue to struggle with OUD developed from the use
9 of prescription opioids. Even where individuals who developed OUD from using
10 prescription opioids have subsequently transitioned to using illicit opioids, the injuries to
11 public health associated with that illicit opioid use (including for example, the increase in
12 needle use and associated harms and the rise in overdose deaths from heroin and
13 fentanyl), would not have occurred to their fullest extent but for Defendants' conduct. *See*
14 *In re Ethan C.*, 279 P.3d at 1071.

15 (b) Defendants' Conduct Was a Proximate Cause of the Public
16 Nuisance Existing in San Francisco

17 28. Proximate cause requires that the opioid crisis existing in San Francisco be a
18 foreseeable consequence of Defendants' conduct. *Novak v. Cont'l Tire N. Am.*, 231 Cal.
19 Rptr. 3d 324, 329 (Ct. App. 2018) (a defendant may be relieved of liability if "it appears
20 to the court highly extraordinary that [the defendant's conduct] should have brought about
21 the harm" (citation and quotation marks omitted)). "[A] public nuisance claim satisfies
22 proximate cause if the defendant's conduct is likely to cause a significant invasion of a
23 public right." *San Francisco MTD*, 491 F. Supp. 3d at 679 (citing *In re Firearms Cases*,
24 Cal. Rptr. 3d 659, 680 (Ct. App. 2005)).

25 29. The opioid crisis existing in San Francisco was a foreseeable consequence
26 of Defendants' conduct. It was foreseeable—and indeed Defendants' intent—that their
27 marketing would increase the supply of prescription opioids in San Francisco. It was also
28 foreseeable that their failure to maintain effective controls against diversion and to stop
shipment or dispensing of suspicious orders unless and until such suspicions were

resolved would lead to diversion and the growth of an illegal secondary market in opioids. Indeed, as this Court has previously recognized, “[t]he very existence of the duties to maintain effective controls supports the notion that opioid misuse is foreseeable.” *San Francisco MTD*, 491 F. Supp. 3d at 690 (citing *Dent v. National Football League*, 902 F.3d 1109, 1119 (9th Cir. 2018) (“A lack of reasonable care in the handling, distribution, and administration of controlled substances can foreseeably harm the individuals who take them. That’s why they are ‘controlled’ in the first place—overuse or misuse can lead to addictions and long-term health problems.”)). Finally, it was foreseeable that increasing the volume of prescriptions, and failing to prevent diversion, would increase addiction, misuse, abuse, overdose and death.

30. It was also foreseeable to Defendants that once individuals developed opioid use disorder, they were likely to seek out illicit opioids, including heroin and fentanyl. The medical literature demonstrates a well-established link between prescription opioid use and later use of illicit opioids like heroin and fentanyl.

31. That the intervening acts of other persons might have contributed to this outcome does not break this chain of causation or render Defendants’ conduct too attenuated from the public nuisance to be proximate. As this Court previously found, Defendants “could reasonably foresee the intervening acts of third parties.” *San Francisco MTD*, 491 F. Supp. 3d at 679. Indeed, in some cases, these actions by third parties were the intended result of Defendants’ misconduct. Defendants’ conduct thus was a proximate cause of the public nuisance.

(c) The Identification of Other Potential Contributors to the Public Nuisance Does Not Negate Defendants’ Role

32. Finally, Defendants argue that their liability is negated by the presence of other factors potentially contributing to the opioid crisis in San Francisco. This argument lacks merit.

33. The substantial factor test does not require that all other contributing causes be ruled out in order to hold Defendants liable for a public nuisance. *ConAgra*, 227 Cal. Rptr. 3d at 543–45; *see also Johnson & Johnson Talcum Powder Cases*, 249 Cal. Rptr. 3d

642, 674 (Ct. App. 2019); *Markow v. Rosner*, 208 Cal. Rptr. 3d 363, 378 (Ct. App. 2016); *Cooper v. Takeda Pharmaceuticals America, Inc.* 191 Cal. Rptr. 3d 67, 92 (Ct. App. 2015). Rather, a defendant is liable for any public nuisance it contributed to, *Cty. of Santa Clara*, 40 Cal. Rptr. 3d at 324–25, and the Court must find that each Defendant’s conduct was a substantial factor in bringing about or sustaining the nuisance. *ConAgra*, 227 Cal. Rptr. 3d at 544–45. That finding, for the reasons set forth above, is well-supported. The fact that other actors or other dynamics may also be impacting the creation, scope, or duration of an opioid-related public nuisance is no defense to nuisance liability. *Wade v. Campbell*, 19 Cal. Rptr. 173, 177–78 (Ct. App. 1962); *see also Judson v. Los Angeles Suburban Gas Co.*, 106 P. 581, 582 (Cal. 1910) (defendant had “no defense” to a public nuisance action based on “other sources of possible discomfort to plaintiff”).

4. *Defendants Are Jointly and Severally Liable*

34. When multiple tortfeasors are each a substantial factor in creating or maintaining a public nuisance, they are jointly and severally liable for that nuisance. *See American Motorcycle Ass’n v. Superior Court*, 578 P.2d 899, 904 (Cal. 1978); *ConAgra*, 227 Cal. Rptr. 3d at 556–57; *Dauenhauer v. Sullivan*, 30 Cal. Rptr. 71, 74 (Ct. App. 1963). Any burden of proving that liability is either divisible or severable is borne by defendants. *Lineaweaver v. Plant Insulation Co.*, 37 Cal. Rptr. 2d 902, 907 (Ct. App. 1995) (“Defendants would not escape liability simply because the precise contribution of each exposure to the disease cannot be determined, but they would be entitled to limit damages assessed against them if they proved the harm was capable of apportionment among them.”); *see also ConAgra*, 227 Cal. Rptr. 3d at 556–57 (affirming trial court’s finding that defendants failed to prove divisibility of public nuisance) (“The wrongdoers should be left to work out between themselves an apportionment.”).

5. *The People Have Proven Their Unfair Competition Law Cause of Action*

35. California Business and Profession Code Section 17200 defines “unfair competition” to include “any unlawful, unfair or fraudulent business act or practice.” The statute uses “broad, sweeping language” to include “anything that can properly be called a

1 business practice and that at the same time is forbidden by law.” *Cel-Tech Commc’ns,*
 2 *Inc. v. Los Angeles Cellular Tel. Co.*, 973 P.2d 527, 539–40 (Cal. 1999); *Bank of the West*
 3 *v. Superior Court*, 833 P.2d 545, 553 (Cal. 1992).

4 36. The fact a party may have believed its conduct was lawful is not a defense:
 5 “intent is not an element of such a violation.” *Hewlett v. Squaw Valley Ski Corp.*, 63 Cal.
 6 Rptr. 2d 118, 130 (Ct. App. 1997). ““The statute imposes strict liability. It is not
 7 necessary to show that the defendant intended to injure anyone.”” *Id.* (quoting *State Farm*
 8 *Fire & Casualty Co. v. Superior Court*, 53 Cal. Rptr. 2d 229, 233 (Ct. App. 1996)).

9 37. In actions brought in the name of the People, reliance and actual damages
 10 need not be shown. *People v. Pacific Land Research Co.*, 569 P.2d 125, 129 n.7 (Cal.
 11 1977) (“In an action by the People, on the other hand, only the violation of statute is
 12 necessary to justify injunctive relief and civil penalties.”). “As an action designed to
 13 protect the public rather than benefit private parties, reliance and actual damages need not
 14 be established. ‘[O]nly the violation of statute is necessary to justify an injunctive relief
 15 and civil penalties.’” *People v. Toomey*, 203 Cal. Rptr. 642, 657 (Ct. App. 1984) (quoting
 16 *Pacific Land Research Co.*, 569 P.2d at 129 n.7).

17 38. The People’s UCL claim is predicated on unlawful business practices, unfair
 18 business practices, and fraudulent business practices, including violations of both the
 19 federal Controlled Substances Act and California’s Consumer Legal Remedies Act. The
 20 People’s UCL claim, asserted against all defendants except Walgreens, is predicated on
 21 unlawful business practices, unfair business practices, and fraudulent business practices,
 22 including violations of both the federal Controlled Substances Act and California’s
 23 Consumer Legal Remedies Act.

24 39. The burden of proof for a claim for violations of the UCL is preponderance
 25 of the evidence. *People v. First Fed. Credit Corp.*, 128 Cal. Rptr. 2d 542, 549 (Ct. App.
 26 2002) (citing *People v. Superior Court (Kaufman)*, 525 P.2d 716, 722 n.9 (Cal. 1974)).

27 40. **Unlawful Business Practices:** Under the “unlawful” prong, Section 17200
 28 “borrows violations of other laws and treats them as unlawful practices that the unfair

1 competition law makes independently actionable.” *Cel-Tech Commc’ns, Inc.*, 973 P.2d at
 2 539–40 (quotation marks and citations omitted). “[V]irtually any law or regulation—
 3 federal or state, statutory or common law—can serve as [a] predicate for a . . . [section]
 4 17200 “unlawful” violation.” *Klein v. Chevron U.S.A., Inc.*, 137 Cal. Rptr. 3d 293, 326–
 5 27 (Ct. App. 2012) (quoting *Paulus v. Bob Lynch Ford, Inc.*, 43 Cal. Rptr. 3d 148, 165
 6 (Ct. App. 2006)). In an action by the People under the “unlawful” prong of the UCL, an
 7 actual injury to the consuming public is not required to be proven as an element. *People*
 8 *ex rel. Van de Kamp v. Cappuccio, Inc.*, 251 Cal. Rptr. 657, 663 (Ct. App. 1988).

- 9 a. The People have proven that each Defendant against whom a UCL claim
 10 is asserted violated the federal CSA, specifically their duties under 21
 11 C.F.R. §§ 1301.71(a) and 1301.74(b). As such, the People have
 12 established that each Defendant violated the unlawful prong of the
 13 Unfair Competition Law. As this Court has previously held,
 14 “California’s UCL permits the [People] to use the CSA’s regulations as
 15 predicate violations that trigger liability.” *San Francisco MTD*, 491 F.
 16 Supp. 3d at 685–86 (citing *Samura v. Kaiser Foundation Health Plan*
 17 *Inc.*, 22 Cal. Rptr. 2d 20, 31 (Ct. App. 1993)).
- 18 b. Likewise, the People have proven additional predicate violations of the
 19 UCL’s “unlawful” prong through evidence that each of the
 20 Manufacturing Defendants violated the CLRA. The CLRA prohibits
 21 certain “unfair methods of competition and unfair or deceptive acts or
 22 practices . . . intended to result or which results in the sale . . . of goods .
 23 . . to any consumer,” including representing that goods “have
 24 sponsorship, approval, characteristics, ingredients, uses, benefits, or
 25 quantities that they do not have,” Civ. Code § 1770(a)(5), or “of a
 26 particular standard, quality, or grade, . . . if they are of another”
 27 § 1770(a)(7), or “disparaging the goods of another by false or misleading
 28 representation of fact.” § 1770(a)(8).

- c. The People have proven by a preponderance of the evidence that each Manufacturing Defendant engaged in deceptive business practices in violation of the CLRA by representing in California that its opioids had characteristics, uses or benefits which they did not have, representing that its opioids were of a particular standard, quality or grade when they were of another, and disparaging the goods of another (specifically, the class of non-steroidal anti-inflammatory drugs (NSAIDs)) through false or misleading representations of fact.
- d. Finally, the People have proven by a preponderance of the evidence that Defendants contributed to a public nuisance, as explained above, in violation of Cal. Civ. Code § 3749 and § 3480. Violations of the Public Nuisance Law are unlawful business practices under the UCL. *People ex rel. Trutanich v. Joseph*, 140 Cal. Rptr. 3d 9, 19 (Ct. App. 2012).
- e. Thus, the People have established that each Defendant violated the UCL under the “unlawful” prong by violating the CSA, the CLRA, and the Public Nuisance Law. *See Comm. On Children’s Television, Inc. v. Gen. Foods Corp.*, 673 P.2d 660, 668 (Cal. 1983).

41. **Fraudulent Business Practices:** A business practice is “fraudulent” within the meaning of section 17200 if it is “likely to deceive the public.” *McKell v. Washington Mutual, Inc.*, 49 Cal. Rptr. 3d 227, 239 (Ct. App. 2006) (citing *Bank of the West*, 833 P.2d at 553; *Massachusetts Mutual Life Ins. Co. v. Superior Court*, 119 Cal. Rptr. 2d 190, 194–95 (Ct. App. 2002)). “It may be based on representations to the public which are untrue, and ‘also those which may be accurate on some level, but will nonetheless tend to mislead or deceive A perfectly true statement couched in such a manner that it is likely to mislead or deceive the consumer, such as by failure to disclose other relevant information, is actionable under’ the UCL.” *Id.* (quoting *Massachusetts Mutual Life Ins. Co.*, 119 Cal. Rptr. 2d at 194; *Prata v. Superior Court*, 111 Cal. Rptr. 2d 296, 302 (Ct. App. 2001)). While a common law “fraudulent deception must be actually false, known to be false by

1 the perpetrator, and reasonably relied upon by a victim who incurs damages,” “[n]one of
 2 these elements are required to state a claim for injunctive relief” under the UCL. *Day v.*
 3 *AT&T Corp.*, 74 Cal. Rptr. 2d 55, 60 (Ct. App. 1998).

- 4 a. The People have proven by a preponderance of the evidence that each
 5 Manufacturing Defendant violated the “fraudulent” prong of the UCL by
 6 marketing and promoting their opioids in California in a false and
 7 misleading manner that was likely to deceive healthcare providers and the
 8 public.
- 9 b. The evidence also establishes that each Manufacturing Defendant may be
 10 held liable under the UCL for the fraudulent statements of third parties—
 11 including front groups, key opinion leaders, and Continuing Medical
 12 Education programs—carried out under their influence and with their
 13 substantial involvement. As this Court previously ruled, “‘Liability may be
 14 imposed on those who aid and abet another’s violation of the UCL if the
 15 individual knows the other’s conduct constitutes a violation and gives
 16 substantial assistance or encouragement to the other to so act.’” *San*
 17 *Francisco MTD*, 491 F. Supp. 3d at 691 (quoting *DeCarlo v. Costco*
 18 *Wholesale Corp.*, No. 14cv00202 JAH-BLM, 2020 WL 1332539, at *5
 19 (S.D. Cal. Mar. 23, 2020)). The evidence establishes that Defendants
 20 exercised sufficient influence and control over these third party
 21 statements—indeed, in many instances Defendants approved and/or
 22 developed these third-party misrepresentations—to be held legally
 23 responsible for these violations of the UCL.

24 **42. Unfair Business Practices:** A business practice may be “‘unfair’ even if not
 25 specifically proscribed by some other law.” *Korea Supply Co. v. Lockheed Martin Corp.*,
 26 63 P.3d 937, 943 (Cal. 2003). The definition of “unfair” under the UCL is currently in
 27 flux. The Ninth Circuit, however, has applied a balancing test that weighs “the harm to
 28 the consumer” against “the utility of the defendant’s practice.” *Lozano v. AT&T Wireless*

1 *Servs., Inc.*, 504 F.3d 718, 736 (9th Cir. 2007); *see also Bardin v. DaimlerChrysler Corp.*,
 2 39 Cal. Rptr. 3d 634, 642 (Ct. App. 2006) (“[A]n unfair business practice occurs when it
 3 offends an established public policy or when the practice is immoral, unethical,
 4 oppressive, unscrupulous or substantially injurious to consumers.” (quotation marks
 5 omitted)).

6 43. Each Defendant engaged in business practices that violated established
 7 public policy and were immoral, unethical, oppressive, or unscrupulous by aggressively
 8 marketing and promoting opioids for the treatment of chronic, non-cancer pain with
 9 knowledge of the hazard and deceptively downplaying the risks and overstating the
 10 benefits. Each Defendant likewise engaged in business practices that violated established
 11 public policy and were immoral, unethical, oppressive, or unscrupulous by failing to
 12 maintain effective controls against diversion and to identify, report, and stop suspicious
 13 orders for prescription opioids.

14 44. This conduct resulted in substantial injury to the public, including an
 15 entirely foreseeable rise in opioid addiction, overdoses, deaths, and other related harms,
 16 and has fueled the opioid crisis in San Francisco.

17 45. The utility, if any, of each Defendant’s conduct, is clearly outweighed by
 18 the substantial injury and gravity of harm to the People in San Francisco.

19 46. Thus, the People have proven by a preponderance of the evidence that each
 20 Defendant violated the “unfair” prong of the UCL.

21 47. **Joint and Several Liability** “As a general matter, parties may be held
 22 jointly and severally liable for unfair competition and for making false and misleading
 23 statements.” *First Fed. Credit Corp.*, 128 Cal. Rptr. 2d at 551; *see also People v. Dollar*
 24 *Rent-A-Car Systems, Inc.*, 259 Cal. Rptr. 191, 192 (Ct. App. 1989) (imposing a civil
 25 penalty jointly and severally against three rental car agencies whose employees made false
 26 and misleading representations to customers); *People v. Bestline Prods., Inc.*, 132 Cal.
 27 Rptr. 767, 770, 796 (Ct. App. 1976) (affirming imposition of joint and several civil
 28 penalty for FAL violations where defendants each made false statements at meetings of

1 distributors of their products). The imposition of joint and several liability is appropriate
2 for the People's UCL cause of action.

3 **B. Defendants' Affirmative Defenses are Unavailing**

4 48. Defendants raised numerous affirmative defenses in their answers to the
5 People's Sixth Amended Complaint. Defendants have the burden of proving these
6 affirmative defenses by a preponderance of the evidence. *Bertero v. Nat'l General Corp.*,
7 529 P.2d 608, 616 (Cal. 1974).

8 49. The People have moved for summary judgment on Defendants' affirmative
9 defenses, which the Court today granted in part. *City and Cty. of San Francisco v. Purdue*
10 *Pharma LP*, No. 3:18-CV-07591-CRB, Dkt. # 1250, (N.D. Ca. April 18, 2022). The
11 People will address the affirmative defenses that have survived summary judgment and
12 for which Defendants present evidence and argument, if any, in subsequent drafts of their
13 proposed FOFCOL.

14 **C. Non-Waiver**

15 Given the preliminary nature of this document, the People reserve all rights with
16 respect to the submission of evidence, of proposed findings of fact, and of proposed
17 conclusions of law, as the parties proceed through the trial. Nothing herein should be
18 construed to limit the People's case in any way or to preclude the People from submitting
19 additional evidence not referenced here, or making legal arguments not addressed in this
20 document.
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CERTIFICATE OF SERVICE

I hereby certify that, on April 18, 2022, service of this document was accomplished pursuant to the Court's electronic filing procedures by filing this document through the ECF system.

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